



## NATIONAL COMMITTEE ON RESEARCH IN THE SOCIAL SCIENCES AND HUMANITIES (NCRSH)

### SOP NO.5: Standard Operating Procedure for Management of Protocol Amendments

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#### Purpose

This SOP describes how protocol amendments are managed and reviewed by NCRSH.

#### Scope

This SOP applies to previously approved study protocols but later being amended and submitted for approval by NCRSH. Amendments made to protocols can not be implemented until they are reviewed and approved by NCRSH.

#### Allowable Exceptions

This SOP is meant to be followed without deviation

#### Specific Procedure

- Secretariat receives the amended protocol
- For minimal risk amendments, expedited review process shall apply as per **SOP No.4**
- For protocols with major amendments, standard review process as per **SOP No.3** shall apply
- Secretariat shall communicate decision of review to investigator in accordance with the chosen review procedure of either SOP No.3 or SOP No.4
- NCRSH requires that an amended protocol must highlight all the specific amendments in the amended protocol for ease of reference
- In addition, the investigator shall submit an application for review of amendments on **Form for Request for Amendment that appears on page 3**

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## **Definition of Terms**

*Protocol amendment:* A change to the study protocol during the planning or course of study.

*Major amendments:* These are protocol changes that affect the safety, physical or mental integrity of the study participants. Examples of these include;

- Changes in the purpose/objectives or design of the study
- Changes in the study procedures
- Changes in the study population( sample size, age range, inclusion and exclusion criteria, study sites/places)
- Changes in the PI to be accompanied by CV of the new PI

## **NCRSH FORM FOR REQUEST OF AMENDMENT**

<b>NCRSH REF NO:</b>  NCRSH will not process requests for amendment without this number	<b>Date of Request</b>
<b>Principal Investigator's Name:</b>  <b>Phone number:</b> <b>E-mail address:</b>	<b>Contact Person (if other than PI)</b>  <b>Phone No:</b> <b>E-mail address</b>
<b>Title of Study:</b>	

1. **Description of proposed changes:**  
(Specify the sections, paragraphs and pages at which the proposed changes appear. Such changes must be highlighted)
  
2. **Reason for amendment /modification:**
  
3. **Changes to consent form:** Are changes required? No \_\_\_\_\_ Yes \_\_\_\_\_ (If yes, attach new consent form)
  
4. **Signature of Principal Investigator:** \_\_\_\_\_ **Date:** \_\_\_\_\_